

	Overnight (reference)	Ambulatory	Hazard Ratio (95% CI)	p value
	no./total no. (%)	no./total no. (%)		
Low ACEF				
MACE	7/618 (1.1)	18/2214 (0.8)	0.716 (0.299 – 1.714)	0.453
Readmission	4/618 (0.6)	16/2214 (0.7)		
All-cause Death	1/618 (0.2)	0/2214 (0)		
MI	4/618 (0.6)	3/2214 (0.1)		
High ACEF				
MACE	35/1098 (3.2)	22/1002 (2.2)	0.683 (0.401 – 1.165)	0.162
Readmission	14/1098 (1.3)	18/1002 (1.8)		
All-cause Death	20/1098 (1.8)	4/1002 (0.4)		
MI	4/1098 (0.4)	1/1002 (0.1)		
ACEF score: age/left ventricular ejection fraction + 1 (if creatinine \geq 2 mg/dl).				

Conclusions: In this single-center registry, patients who underwent ambulatory PCI had no worse outcomes than those who stayed at least one night, at high and low ACEF scores.

TCT-656

Low Incidence of Stent Thrombosis in Asian Races: Multicenter Registry in Asia 7 Years Follow-Up Result

Sunao Nakamura¹, Hisao Ogawa², Jang-Ho Bae³, Yeo Cahyadi⁴, Wasan Udayachalerm⁵, Damras Tresukosol⁶, Sudaratana Tansuphaswadikul⁷
¹New Tokyo Hospital, Chiba, Japan, ²Kumamoto University Hospital, Kumamoto, Japan, ³Konyang University Hospital, Daejeon, Korea, Republic of, ⁴Husada Hospital, Jakarta, Indonesia, ⁵King Chulalongkorn Memorial Hospital, Bangkok, Thailand, ⁶Faculty of Medicine Siriraj Hospital, Bangkok, Thailand, ⁷Chest Disease Institute, Nonthaburi, Thailand

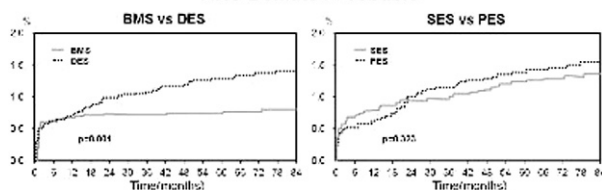
Background: The aim of this study was to evaluate the frequency, predictors and the clinical outcome of stent thrombosis after DES implantation and bare metal stent (BMS) implantation in Asian races.

Methods: A total of 14,577 consecutive patients who underwent successful DES implantation (8,809 patients, 62% of the lesion with Sirolimus-eluting stent: SES, 38% of the lesion with Paclitaxel-eluting stent: PES) and BMS implantation (5,768 patients) were included in this study. We evaluate the frequency, predictor of stent thrombosis.

Results: At a mean follow-up of 78.5 \pm 29.9 months in DES and 81.8 \pm 26.4 months in BMS. The cumulative incidence of stent thrombosis were subacute stent thrombosis (SAT): 0.5% with DES and 0.6% with BMS, late stent thrombosis (LAST): 0.18% with DES and 0.1% with BMS, very late stent thrombosis (VLAST): 0.18% per year with DES and no BMS. Independent predictors of stent thrombosis are bifurcation lesion (OR=1.90, 95% CI: 1.83 to 24.24, p=0.01) and ejection fraction (OR=0.90, 95% CI: 0.86 to 0.94, p=0.03). Only 0.2 % of the patients were died because of the myocardial infarction after stent thrombosis in both groups.

Conclusions: The incidence of stent thrombosis in Asian races is relatively low (0.5 % with DES and 0.6% with BMS of SAT, 0.18% increase per year with DES of late stent thrombosis) at mean follow-up to 7 years. Particular attention will need to be directed to this complication when the patients have bifurcation lesions or low ejection fraction.

Stent Thrombosis to 7 Years ARC Definite / Probable



TCT-657

Multi Center, Prospective, Randomized, Single Blind, Consecutive Enrollment Evaluation Of Elixir DESyne™ Novolimus-Eluting Coronary Stent System With Durable Polymer To Endeavor Zotarolimus-Eluting Coronary Stent System: 3-Year Clinical and 9-Month Angiographic And IVUS Results: EXCELLA II Study

Stefan Verheye¹, Christophe Dubois², Karl-Eugen Hauptmann³, John Ormiston⁴, James Stewart⁵, Joachim Schofer⁶, Karl Stangl⁷, Bernhard Witenbichler⁸, Marcus Wiemer⁹, Emanuele Barbato¹⁰, Peter Fitzgerald¹¹, Hiromasa Otake¹², Patrick W. Serruys¹³

¹Antwerp Cardiovascular Center, ZNA Middelheim, Antwerp, Belgium, Antwerp, Belgium, ²Catholic University Leuven, Leuven, Belgium, ³Krankenhaus der Barmherzigen Brüder Trier, Trier, Germany, ⁴Associate Professor, University of Auckland Medical School, Auckland, New Zealand, ⁵Auckland City Hospital, Auckland, New Zealand, ⁶Medicare center Prof Mathey, Prof Schofer, Hamburg University Cardiovascular Center, Hamburg, Germany, ⁷Charité University Hospital, Humboldt University, Berlin, Germany, Berlin, Berlin, ⁸Charité Campus Benjamin Franklin, Berlin, Germany, ⁹Herz-und Diabeteszentrum Nordrhein-Westfalen, Bad Oeynhausen, Germany, ¹⁰Cardiovascular Center Aalst, Aalst, Belgium, ¹¹Cardiovascular, Stanford, California, ¹²Kobe University Graduate School of Medicine, Kobe-city, Hyogo, ¹³Thoraxcenter, Erasmus Medical center, Rotterdam, Netherlands

Background: Aims: To evaluate safety and effectiveness of the Elixir DESyne™ Novolimus-Eluting Coronary Stent System (CSS) compared to the Endeavor Zotarolimus-Eluting CSS through assessment of clinical, angiographic, and IVUS endpoints.

Methods: 210 patients were randomized 2:1 either to the DESyne CSS loaded with 5mcg per mm of stent length of Novolimus, a sirolimus metabolite, eluted via a durable methacrylate polymer, or to the Endeavor CSS loaded with 10mcg per mm of stent length of Zotarolimus eluted via a durable phosphoryl choline polymer. All patients were analyzed for the primary endpoint of late lumen loss (LLL) assessed by QCA at 9 months. All patients also underwent evaluation for secondary endpoints which included a Device-orientated Composite Endpoint (DoCE) defined as: cardiac death, MI not clearly attributable to a non-intervention vessel, and clinically-indicated target lesion revascularization (TLR); clinically-indicated Target Vessel Revascularization (TVR); and stent thrombosis all evaluated at 1, 6, 9, and 12 months and annually through 5 years. Stents were also assessed for angiographic endpoints at 9 months including: in-stent and in-segment LLL. A subset of patients underwent IVUS evaluation including percent neointimal obstruction at 9 months. The study met the non-inferiority endpoint and also demonstrated superiority of the DESyne CSS as compared to control.

Results: Table 1 summarizes 9-month angiographic and IVUS results and clinical results through 2 years which trend lower for the DESyne stent.

Table 1: 9-month Angiographic, IVUS and Clinical Results

	DESyne	Endeavor	p-value
Angiographic Results			
Baseline RVD (post-procedure)	2.84 \pm 0.43	2.91 \pm 0.38	0.2
9-month angiographic/IVUS			
In-stent LLL	0.11 \pm 0.32	0.63 \pm 0.42	< 0.001
% neointimal volume	4.5 \pm 5.1	20.9 \pm 11.3	<0.001
Clinical Results			
12-month DoCE (%)	4.3	7.0	0.51
Clinically-indicated TLR	1.4	5.6	0.18
24-month DoCE (%)	4.3	9.0	0.14
Clinically-indicated TLR	1.4	7.0	0.045

Conclusions: The study met the non-inferiority endpoint and also demonstrated superiority of the DESyne CSS as compared to control. Clinical results through 3 years and a review of angiographic and IVUS results will be presented.

TCT-658

Do Drug Eluting Stents Improve Survival in All Comers?

Tudor Vagaonescu¹, Yingzi Deng¹, Abel Moreyra¹, John Kostis²
¹UMDNJ, New Brunswick, NJ, ²CVI & RWJMS, UMDNJ, New Brunswick, NJ

Background: Drug eluting stents (DES) have been shown to significantly decrease restenosis with subsequent need for lesion and/or vessel revascularization when compared with bare metal stents (BMS) in selected patient groups in both randomized controlled trials and in observational registries. If their use in all-comers is also associated with a survival benefit over a longer follow-up is controversial.

Methods: Retrospective analysis of the MIDAS registry for patients who underwent PCI with BMS between January 1 1997-December 31 1998 (pre DES era, group 1; N=

19045), and patients who underwent PCI with BMS (group 2; N=12559) and DES (group 3; N=19346) between January 2003- December 31 2004 (DES era). All cause and cardiovascular mortality was followed for all groups for 5 years.

Results: At 5 year follow up the unadjusted all- cause mortality was significantly higher in group 2 (18.41%; $p=0.003$) when compared with group 1 (14.01%) and group 3 (13.27%). The unadjusted cardiovascular mortality was significantly lower in group 3 (5.68% vs. 7.66% in gr 1 and 9.01% in gr 2; $p<0.0001$). After adjusting for baseline characteristics such as age, sex, race, diabetes, hypertension, renal disease, anemia, cancer, cerebrovascular disease and left ventricular dysfunction there was a survival benefit associated with DES; the hazard ratios for total mortality and cardiovascular mortality were 0.74 (95% CI 0.70 to 0.78; $p<0.0001$) and 0.58 (95% CI 0.53 to 0.63; $p<0.0001$) respectively. For the patients from group 3 there was a significant survival benefit for cardiovascular mortality (HR 0.83; CI 0.77-0.90; $p<0.0001$) but not for total mortality (HR 0.96; CI 0.91-1.02; $p=0.16$) after adjustment for baseline characteristics.

Conclusions: In contemporary practice there appears to be a baseline selection bias in the choice of stent type used during a PCI, with BMS being preferentially used in sicker patients. This translates in a survival benefit in patients receiving DES, which may explain the discrepancies in survival between stent registries and RCT.

TCT-659

Trends in Revascularization and Mortality for BMS and DES Coronary Stenting Procedures: A Medicare Study of 156,300 patients

Jasmine Patel¹, Kevin Ong¹, Heather Watson², Carrie Kuehn³, Jorge Ochoa³

¹Exponent, Philadelphia, PA, ²Exponent, Menlo Park, CA, ³Exponent, Bellevue, WA

Background: It is now common practice to use coronary stents following PTCA to restore blood flow in patients with CAD. The purpose of this study is to evaluate the utilization of bare-metal stents (BMS) and drug-eluting stents (DES) and their revascularization and mortality rates in the U.S. from 1997-2009.

Methods: The Medicare 5% LDS analytical files were queried to identify patients with BMS and DES between 1997-2009 using ICD-9-CM. The subsequent rates of revascularization and mortality were evaluated.

Results: A total of 88,000 BMS procedures were identified between 1997-2009 with a revascularization rate of 31%. In addition, 68,300 DES procedures were identified from 2002-2009 with an overall revascularization rate of 19%. Within 2 years of FDA approval, the DES dominated the stent market, accounting for 88.4% of all coronary stent procedures in 2005. Due to DES safety concerns of late stent thrombosis, BMS utilization increased steadily to 37% in 2007 with a simultaneous decrease in DES usage. revascularization burden increased considerably from 8.2% in 1997 to 44.2% in 2009 for BMS. The revascularization burden for DES increased at the same rate from 2006-2009. The majority of patients undergoing stenting procedures were also diagnosed with hypertension (75-85%) with revascularization rates higher among this population than primary procedures. Over 60% of patients undergoing a DES stenting procedure (primary or revascularization) are implanted with one stent while 27% are implanted with two stents and less than 10% receive 3 or more stents. The same trend was observed for patients undergoing primary or revascularization BMS procedures. Ten-year Kaplan Meir mortality rates were also assessed among the DES and BMS patient populations. The average hospitalization charges for primary DES procedures was \$64,000, whereas the average charges for BMS procedures were \$10,000-23,000 lower than DES procedures.

Conclusions: Temporal trends showed that concerns about late-stent thrombosis with use of DES led to a sharp decline in utilization. Analysis of mortality and revascularization following BMS and DES procedures provided information about the comparative safety and effectiveness of these procedures.

TCT-660

Incidence and Predictors of Stroke Following Percutaneous Coronary Intervention in United States

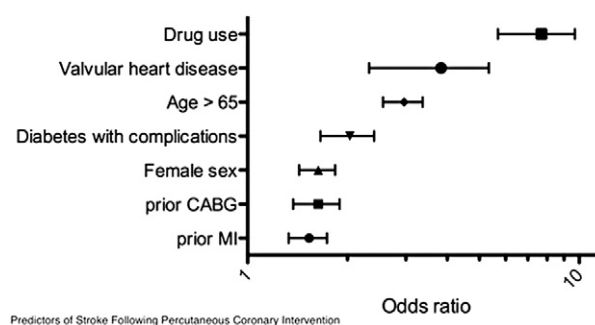
Vladimir Iakhter¹, Chad Zack¹, Paul Hermans², Alfred Bove¹, Paul Katz¹, Riyaz Bashir¹

¹Temple University School of Medicine, Philadelphia, PA, ²Temple University Hospital, Philadelphia, PA

Background: Acute cerebrovascular episode (CVA) following percutaneous coronary intervention (PCI) is a rare but devastating complication. We sought to determine the incidence and predictors of stroke following PCI in United States.

Methods: The Nationwide Inpatient Sample (NIS) database was used to identify all patients who developed acute CVA following PCI between January and December 2009. Risk adjusted logistic regression was performed to identify independent predictors of acute stroke following PCI.

Results: Of the 444,326 patients who underwent PCI, 437 (0.1%) acute strokes were identified. The in-hospital mortality rate in patients who developed stroke was significantly higher than in control group (2.3% vs. 0.6%, $p < 0.01$). Independent predictors of stroke following PCI were history of drug abuse (OR 7.2, 95% CI [4.5 - 11.4], $p < 0.01$), valvular heart disease (OR 3.2, 95% CI [1.6 - 6.7], $p < 0.01$), age > 65 (OR 2.9, 95% CI [2.3 - 3.7], $p < 0.01$), diabetes with complications (OR 2.0, 95% CI [1.4 - 2.7], $p < 0.01$), female sex (OR 1.6, 95% CI [1.3 - 2.0], $p < 0.01$), history of coronary artery bypass grafting (OR 1.6, 95% CI [1.2 - 2.1], $p < 0.01$) and history of myocardial infarction (OR 1.5, 95% CI [1.2 - 1.9], $p < 0.01$).



Conclusions: In this observational study we found that risk of stroke following PCI is low, whereas the in-hospital mortality associated with this complication is high. The independent predictors of stroke complication include history of drug abuse, valvular heart disease, advanced age, diabetes with complications, prior CABG or MI.

TCT-661

Clinical Relevance of Endothelial Dysfunction after Everolimus-Eluting Stent Implantation Compared to First Generation Drug-Eluting Stent.

Yoshifumi Nakajima¹, Kengo Tanabe¹, Jiro Aoki¹, Takuya Hashimoto¹, Kazuyuki Yahagi¹, Makoto Nakashima¹, Shuzou Tanimoto¹, Hiroyoshi Nakajima¹, Kazuhiro Hara¹

¹Mitsui Memorial Hospital, Tokyo, Japan

Background: Endothelial dysfunction of coronary artery has been reported in patients following the first generation drug eluting stent (DES) implantation. However, the incidence and clinical relevance of the second generation DES-induced endothelial dysfunction have not been fully investigated. The aim of this study was to estimate the incidence and clinical relevance of endothelial dysfunction after implantation of everolimus-eluting stent (EES).

Methods: Since June 2006 until August 2011, the present study enrolled 757 patients who were treated solely with DES for de novo lesions, from our prospective institutional database. The patients (279 patients with sirolimus-eluting stent (SES), 210 patients with paclitaxel-eluting stent (PES), and 268 patients with EES) were requested to undergo 8-month follow-up angiography. Endothelial function was evaluated, in case the patients had angina symptom and/or positive exercise electrocardiogram test without in-stent restenosis at the time of follow-up angiography by infusion of incremental acetylcholine and isosorbide dinitrate into the coronary artery. Vascular responses were quantitatively measured in segments proximal, distal, proximal reference and distal reference to DES location. Endothelial dysfunction was defined as abnormal vasoconstriction of $\geq 3\%$ mean vessel diameter changes.

Results: Follow-up angiography was performed in 624 patients (82.4%) of the 757 patients. There were 59 patients (7.8%) who met the inclusion criteria for endothelial function test, 25 patients (8.9%) with SES, 15 patients (7.1%) with PES, 19 patients (7.1%) with EES. In all the 3 groups significant vasoconstriction after acetylcholine infusion was observed in segments distal to stents compared to baseline ($p < 0.05$). Vasodilation in response to isosorbide dinitrate infusion was also observed. Endothelial dysfunction was quantitatively assessed in all the 59 patients at distal segments to DES. No significant differences were observed in percent diameter changes from baseline among the groups.

Conclusions: Clinically relevant endothelial dysfunction following EES implantation seems to be present in approximately 7%, which is similar to the first generation DES implantation.

TCT-662

One Year Outcomes Following PCI in Patients with Asymptomatic CAD: A Report from the NHLBI Dynamic Registry

Mohun Ramratnam¹, Faith Selzer², Dustin Kliner¹, Catalin Toma¹, Sameer Khandhar¹, Sherry Kelsey², David Williams³, Oscar Marroquin¹, Suresh Mulukutla¹

¹Heart and Vascular Institute, University of Pittsburgh Medical Center, Pittsburgh, PA, ²University of Pittsburgh, Pittsburgh, PA, ³Harvard University, Boston, Massachusetts

Background: The level of appropriateness of PCI in the appropriate use criteria (AUC) are based on degree of symptoms and abnormalities on stress testing. Using these criteria, PCI in patients with asymptomatic CAD (ACAD) is often labeled as inappropriate. However, whether this is due to increased harm or perceived decreased benefit, is not clear. Furthermore, many PCI's performed for other instances not related to angina (i.e. CHF, arrhythmias) and are not included as reasons for PCI in the AUC. Therefore, we sought to investigate the outcomes of patients undergoing PCI for asymptomatic CAD compared to those with stable angina (SA).